APPLICATION PROCEDURES FOR EXTERNAL HELIX DATA REQUEST AND TRANSFER

I. PURPOSE OF THE PROCEDURES

- To make data for research purposes easily available, by providing researchers outside the Consortium access to the HELIX data warehouse for work on specified manuscripts.
- To guarantee adherence to cohort data access rights, data protection regulations, and ethics approvals relevant to the cohorts participating in HELIX.

II. CONTENT OF THE HELIX DATA WAREHOUSE

The HELIX data warehouse contains

1) HELIX foreground data (i.e. data generated by the HELIX study)
2) Cohort background data (i.e. data originally generated by the individual cohorts)

A summary of these datasets can be found in ANNEX II and researchers can search available HELIX metadata in the following location: www.projecthelix.eu/data-inventory

III. WHO CAN APPLY FOR ACCESS TO DATA?

Researchers external to the HELIX Consortium who have an interest in using data held in the HELIX warehouse for research purposes can apply for access to data for a specific manuscript at the time. The analysis of these data will be considered outside the remit of the HELIX project. The applicant has to be affiliated with an institution with competence in conducting research projects and which has agreed to be responsible for the conduct of the proposed manuscript. Junior researchers must have a scientific supervisor belonging to such an institution. All proposed manuscripts must have a principal investigator with scientific responsibility for the project. For each accepted proposal, a data transfer agreement (DTA) will be signed between the cohorts participating in HELIX, and the receiving institution.

IV. WHO DECIDES?

The applications are received by the HELIX Coordinator, and are processed and approved by the HELIX Project Executive Committee. The decision to accept or reject a proposal is taken by the HELIX Project Executive Committee. This decision will be based largely on potential overlap with other HELIX-related work, the adequacy of data protection plans, and the adequacy of authorship and acknowledgement plans.

After approval by the HELIX PEC, the cohorts participating in HELIX will each be asked if they approve use of their data in the proposal and what their conditions are for participation. Each cohort will have the opportunity to opt out at this stage if any of their cohort-specific conditions are not met. These conditions are to be stated clearly by the cohort at this stage and the cohort should be open to discussing how these conditions could be fulfilled in subsequent proposal revisions.

V. HOW TO APPLY FOR ACCESS TO DATA OR BIOLOGICAL SAMPLES ?

To apply for access to data contained in the HELIX data warehouse or biological materials obtained by HELIX, the electronic application protocol should be followed (see ANNEX I at the end of this protocol), using the provided 'Data Analysis Request' form.

All applications should be sent to helixdata@isglobal.org.

VI. WHAT PROCEDURES WILL BE FOLLOWED AFTER RECEIPT OF AN APPLICATION?

Upon receipt of the proposal, the following procedure will be followed:

1) The project coordinator appoints one person from within the HELIX Executive Committee to give detailed evaluation of the proposal – is it in line with the HELIX publication policy? Is there overlap with other analyses and proposals? Is co-authorship clearly specified in the proposal? etc. For access to biological samples, the evaluation will establish whether there is enough sample volume available for the proposed analysis, and what the analysis adds to the already available data in the HELIX database.
2) This person provides comments to the PEC (within 2 weeks)
3) The PEC adds comments
5) Each participating cohort is asked whether or not they approve use of their data in the proposal and what their conditions are for participation (within 2 weeks) (see under section IV).
6) The PEC approves/does not approve the proposal (within 4 weeks) and provides the external researchers with feedback on participation conditions of the individual cohorts. Revisions will be requested where relevant.
7) Data transfer agreements (DTAs) will be signed between the cohorts participating in HELIX, and the receiving institution based on the approved proposal.
8) Upon signature of the DTAs, a request for the data set in question will be made by the applicant to the HELIX Database Manager. The requested set of variables and the dataset is loaded onto the ISGlobal server for remote access. To enable analysis, an Xming nserver needs to be installed by the accessing party, using PuTTY SSH-client for connection to the ISGlobal server, following which a suitable statistical software package (like STATA) can be opened through prompting in UNIX. Hence, applicants will be able to analyse the data remotely, but cannot physically download the dataset for local use.

VII. WHAT KIND OF ACCESS IS GRANTED?

Access is granted to data from the HELIX Central Database. Detailed information regarding the contents of the database can be found www.projecthelix.eu/data-inventory. Only data without personal identifiers are available for access – no names, dates of birth, addresses, geocodes, or other data specified as sensitive by the individual cohorts, will be provided. No exclusive rights to the data are given.

The provided data can only be used for analyses specified in the proposal. However, exclusive rights to publish on specific research questions for a limited period of time (to be agreed with the responsible researchers) are granted. After this time limit the dataset and specific research questions will be open to others. A historical file of the data will be stored in case any researcher needs to go back to these data. Acknowledgement of the HELIX project will be required.

VIII. WHAT SHOULD BE INCLUDED IN THE APPLICATION?

This is described in the application form. The applicant should specify the objectives, institution, responsible person, co-workers, title and purpose, and include a short description of the proposed project and of the data needed. A detailed description of the project is requested as annex to the request form.

Documents requested in addition to the completed data request form:

1. Scientific project proposal (protocol) introduction/justification, objectives, analysis plan (including exposures, outcomes, main covariates, and statistical analysis plan), foreseen time line, publication and authorship plan

2. CV of the principal investigator for the last 5 years

Regarding the publication and authorship plan, all HELIX cohorts and those researchers contributing specific work or data to the proposal (e.g. omics, GIS, chemical biomarkers, …) should be offered co-authorship, and authorship of all papers using HELIX data will follow the Vancouver Protocol guidelines. A first list and ranking of authors should be proposed in the proposal; the PEC evaluation will include an evaluation of the adequacy of proposed co-authorship.

The HELIX Consortium must be informed of all changes in approved proposals. Any changes must be approved by the HELIX Project Executive Committee before any manuscript is submitted.

Please consult [weblink] to see the thus far approved proposals.

IX. WILL ANY FEES BE CHARGED?

Approved proposals will be charged a fee for the preparation of HELIX data. This fee will reflect the true costs to the HELIX Project in providing the requested resources, and will relate exclusively to the time spent by the HELIX data manager to extract the data, prepare the analysis files, and answer questions related to the data. Costs are decided on a project to project basis in agreement with the PEC, but will normally be expected to be around 5-10 working day equivalents (750-1500 euros).

Access to biological samples will be charged separately and include fees for extraction of samples from the respective biobanks, shipments, and any other sample processing related costs.

MoBa may charge a fee per article published (around 3000 euros). Details on this will be given in their participation conditions (section VI above) and will depend on whether the requested data includes MoBa background data (ANNEX II).

X. APPROVALS FROM REGULATORY BODIES

It is important that all research based on data from the HELIX project meets requirements of privacy and research ethics, and all approvals must be available for the HELIX Project Executive Committee before any transfer of data is to be arranged.

For access to MoBa background data, approval is required from the National Ethics Committee in Norway (REK) and from the MoBa steering committee. Further, MoBa may charge a fee per article published (see above).

XI. RULES FOR PUBLICATION

All manuscripts and abstracts must be sent to the HELIX Coordinator (helixdata@isglobal.org) one month before they are submitted for publication. The HELIX Project Executive Committee will assess if the use of the data is according to conditions specified in the signed agreements on rights to analyses and follows the agreed authorship and acknowledgement texts.

Study data sets requested by journals: The HELIX Coordinator needs to be notified in cases where the publishing journal requires the submission of the data set studied.

The acknowledgement section of a paper should include a reference to the funding which has led to the generation of the HELIX data. In addition, this section should be used to thank persons who contributed substantially to the work of the project. All publications shall include the following statement:

"The [specify type of data] data of the [specify cohort(s)] provided to this research leading to these results has received funding from the European Community's Seventh Framework Programme (FP7/2007-2013) under grant agreement no 308333 – the HELIX project."

This statement will have to be translated into the language of the publication, if not English.
Other cohort specific statements may need to be included.

XII. ROUTINES IN CASE OF VIOLATION OF ACCORDANCE BETWEEN MANUSCRIPTS AND APPROVED PROJECT DESCRIPTION

In case of suspicion of violation of accordance between manuscripts and approved research questions from the project descriptions, the project investigator/manuscript author will be contacted for clarification. If agreement between partners can not be achieved, and the case is considered as a break in the agreement the following reactions will be considered:

- A written notification will be sent to project responsible institute informing that the project investigator has overstepped the agreement of rights to analysis.
- A written notification will be sent to editors of journals where the manuscript has been submitted informing about the situation.
- Rights of analysis will be withdrawn from the project.

XIII. CONFLICT OF INTEREST BETWEEN APPROVED EXTERNAL PROJECTS

Although the procedures in place attempt to avoid conflicts between approved projects, in case of a potential conflict - e.g. due to changes in the study design - project investigators will be contacted and asked to inform the HELIX Project Executive Committee. The HELIX Coordinator will be responsible for contacting the projects where the conflicts on specific study objectives occur. Possible collaboration should be considered between potential projects.

XIV. ACCIDENTAL FINDINGS

In case of accidental findings, the applicant is required to notify the HELIX Coordinator to communicate the matter, to which a decision will be made with the implicated cohort(s). The applicant will not undertake any further action, nor will the applicant publish details on these findings.

ANNEX I - Application Form for External Collaboration
"DATA ANALYSIS REQUEST"

Please submit one form for each application to: helix@isglobal.org

I. GENERAL INFORMATION

1. PROJECT TITLE (in English)

2. PRINCIPAL INVESTIGATOR (PI)			
Name:		Position / Academic degree:	
Institution:			
Department:			
Address:			
Postcode:	City:	Country:	
Telephone:	Telefax:	Mobile:	E-mail:

3. MASTER, Ph.D or POST DOC PROJECT			
Name of student:		Master, PhD, Post Doc:	
Place of study (University/Institution):			
Department/Institute:			
Address:			
Postcode:	City:	Country:	
Telephone:	Telefax:	Mobile/Cell:	E-mail:

4. COLLABORATORS					
Name:	Position:	Institution:	Telephone:	E-mail address:	Data access? (Yes or No)

5. MANUSCRIPT DESCRIPTION	
A) Specific objectives	
B) Short project summary (full research protocol is required in	

attachment)	
C) Tentative title of manuscript planned from this study	
D) Keywords (3-8 descriptive keywords)	
E) Research timetable	Project start (dd/mm/yyyy): Project end (dd/mm/yyyy): Comments:

6. FUNDING

Please give details on how the project will be funded:

Has the project been/will the project be peer reviewed?
If yes, by what organisation?
Has funding been sought?*
What is the deadline for application to the funder?
Other relevant details:

*Please note that applications for funding must be reviewed PRIOR to submission to a funding body and should be received AT LEAST 6 weeks before the submission deadline.

7. AUTHORSHIP

Please give details on the authorship policy and make sure authorship adheres to the HELIX publication policy:

8. FURTHER INFORMATION

II. APPLICATION FOR DATA

9. DATA SOURCES	
A) HELIX data source(s) – indicate which cohorts and which parts of the study (entire cohorts, subcohort, child panel, pregnancy panel)	Cohorts: INMA (Spain), BiB (UK), EDEN (France), MoBa (Norway), Rhea (Greece). HELIX Subcohort: INMA (Spain), BiB (UK), EDEN (France), MoBa (Norway), Rhea (Greece). HELIX Child Panel: INMA (Spain), BiB (UK), EDEN (France), Rhea (Greece). HELIX Pregnancy Panel: Barcelona, Oslo, Poitiers.
B) Other data sources	Will data from other sources (projects other than HELIX or your own data collection) be utilised? If yes, please specify:
C) Do you apply for linking/merging data files from different sources?	Describe the data files and the linkage:
D) Describe the data set required from HELIX, including the number of subjects.	
E) Does the project request access to HELIX biological samples, and if so, describe in detail which samples. (Material transfer agreements (MTAs) will be needed between each cohort and the processing lab.)	Describe the biological samples requested Include question if requesting laboratory is covered by a relevant national authority?

10. EVALUATION/PERMISSION FROM REGULATORY BODIES	
A) Does the project require separate ethics approval?	If yes, please enclose a copy of the application and/or approval letter.
B) Are permissions required from other data owners or sources?	If yes, please state from whom and attach a copy of the permissions
C) Further information regarding permissions:	

11. NUMBERED LIST OF ATTACHMENTS	
Submission date	
Please enclose the following attachments	1. A complete research protocol including: introduction/justification, objectives, analysis plan (including exposures, outcomes, main covariates, and statistical analysis plan), foreseen time line, publication and authorship plan 2. A CV for the Project Leader covering the last 5 years

Data Use Agreement

The information obtained in any study using HELIX data is of a highly confidential nature and has been given by the study participants on the understanding that it will be treated in the strictest confidence. It is therefore essential that anyone using HELIX data i) reads the data access policy documents* setting out the rules governing access to and use of HELIX data and ii) signs and returns this section as part of the proposal.

Core rules governing data access

1. I will keep the data confidential and will not try and identify study participants;
2. I will submit any papers or conference proceedings concerning results of research with HELIX data to the HELIX Project Executive Committee (PEC) for approval at least 6 weeks before submission;
3. I will only use the data to carry out the research which has obtained approval from the HELIX PEC;
4. I will seek approval prior to my testing hypothesis that lie outside the remit of the approved research proposal/s;
5. Following completion of a research project, I will ensure that HELIX is provided with the final data set and any derived variables used therein for inclusion in the HELIX resource;
6. I will be able to access and analyse the data remotely, and will thereby not share data with researchers outside of my research team;
7. I will not attempt to match data provided for one project to that provided for another project;
8. I will ensure that HELIX has a full and current list of all members of my research team & that a copy of this form is signed and returned by anyone who has access to the data

I have read the documents* setting out the rules governing access to and use of HELIX data and agree to abide by these rules including but not limited to those above:

Name:	
Signature:	Date:
Email:	
Institution:	
Address:	
Role in research project:	
Project Title:	
Project B Number:	

*

ANNEX II – SPECIFICATION OF CENTRAL DATA

Data warehouse

	HELIX Foreground	Cohort background
ENTIRE COHORTS		
Prenatal covariates (requested)		√
Postnatal covariates (requested)		√
Other pregnancy and birth vairables		√
Height/weight measures (requested)		√
Blood pressure (requested)		√
Skinfolds/circumferences (requested)		√
Cognitive assesments (requested)		√
Behavioural assessments (requested)		√
Asthma questions (requested)		√
Lung function (requested)		√
Prenatal GIS exposures	√	
Prenatal Water DBP	√	
Postnatal GIS exposures	√	
SUBCOHORT		
QuestSYS questionnaires (except clinical)	√	
CBCL & Conners	√	
Clinical data sheets	√	
Spirometry data	√	
Neurodevelopmental outcomes	√	
qGIS geocodes	√	
GIS exposures - pre and postnatal	√	
Water DBP	√	
Indoor air models	√	
Biomarker data - pre and postnatal	√	
Child PANEL		
QuestSYS questionnaires (except clinical)	√	
Clinical data sheet P2	√	
Spirometry data	√	
Smart phone data	√	
UV data	√	
Microathelometer data	√	
PM2.5 filter weights	√	
BTEX/NO2 Passive sampler	√	
Biomarker data (non-persistent)	√	
GIS exposures	√	
PREGNANCY PANEL		
QuestSYS questionnaires (except clinical)	√	
Clinical data sheets (inc. Blood pressure)	√	
Hospital birth data	√	
Smart phone data	√	

UV data	√
Microathelometer data	√
PM2.5 filter weights	√
BTEX/NO2 Passive sampler	√
Biomarker data (non-persistent)	√
GIS exposures	√
OMICS	
metabolomics urine	√
metabolomics serum	√
proteomics plasma	√
DNA methylation	√
Transcriptomics	√